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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,532	08/03/2001	Endre Markovits Schersl	22106965.105181	9018
51738 7590 05/25/2007 BAKER & MCKENZIE LLP Pennzoil Place, South Tower 711 Louisiana, Suite 3400 HOUSTON, TX 77002-2716			EXAMINER BADIO, BARBARA P	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 05/25/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/922,532	<b>Applicant(s)</b> SCHERSL ET AL.	
	<b>Examiner</b> Barbara P. Badio, Ph.D.	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 57 and 59-63 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57 and 59-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application.                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

**First Office Action on the Merits of a RCE**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 30, 2007 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

3. The rejection of claims 56 and 58 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is made moot by the cancellation of the instant claims.
4. The rejection of claims 59 and 60 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

***Claim Rejections - 35 USC § 103***

5. The rejection of claims 56 and 58 under 35 USC 103(a) over Fuenzalida et al. (EP 952,208), Sorkin, Jr. (US 5,695,239), Gamble et al. (US 6,596,776), Cleary (US 4,495,094z0, Milstein et al. (US 6,394,230) and Jones et al. (Metabolism, 1998) in combination is made moot by the cancellation of the instant claims.

6. The rejection of claims 57 and 59-63 under 35 USC 103(a) over Fuenzalida et al. (EP 952,208), Sorkin, Jr. (US 5,695,239), Gamble et al. (US 6,596,776), Cleary (US 4,495,094z0, Milstein et al. (US 6,394,230) and Jones et al. (Metabolism, 1998) in combination is maintained.

Applicant's argument centers around the lack of teaching by the references of the specific concentrations of each of the individual policosanols recited by the instant claims. Applicant's argument was considered but not persuasive for the following reasons.

Applicant argues the references do not teach the specific concentrations of each of the policosanols in the claimed composition. According to applicant, the optimization of ranges as obvious based on routine experimentation cannot be applied to compositions that essentially fail to include one or more major components. Thus, applicant argues absence some motivation said routine experimentation couldn't be relied upon.

The following are well known in the art: (a) the use of policosanols in lowering plasma cholesterol levels and (b) the use of combination therapy in the medical art.

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The court has held that it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980). Thus, the combination of two or more of policosanols for the same use would have been obvious to the skilled artisan in the art at the time of the present invention. The motivation to make said combination, including the addition of docosanol, is based on the prior art teachings that said compounds are useful in lowering cholesterol levels. The court has also held that selecting proportions and ranges is not patentable absent a showing of criticality. *In re Russell*, 439 F.2d 1228, 169 USPQ 426 (CCPA 1971). The present specification lacks showing of the criticality of the claimed ranges and, thus, is not patentable over the prior art.

For these reasons and those given in the previous Office Action, the rejection of claims 57 and 59-63 under 35 USC 103(a) over Fuenzalida et al. (EP 952,208), Sorkin, Jr. (US 5,695,239), Gamble et al. (US 6,596,776), Cleary (US 4,495,094z0), Milstein et al. (US 6,394,230) and Jones et al. (Metabolism, 1998) in combination is maintained.

### ***Telephone Inquiry***


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
May 24, 2007